DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-976/S-009

Schwarz Pharma, Inc.
Attention: Ms. Donna K. Multhauf
P.O. Box 2038
Milwaukee, WI 53201-2308

Dear Ms. Multhauf:

Please refer to your supplemental new drug application dated May 25, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Levatol (penbutolol sulfate) 20 mg Tablets.

We acknowledge receipt of your submission dated December 21, 2000.

This supplemental new drug application provides for final printed labeling revised as follows:

1. Addition of, "Rx Only," before the Description section.

2. Under PRECAUTIONS, "Usage in Children" has been changed to "Pediatric Use."

3. Under PRECAUTIONS, the following subsection has been added in accordance with 21 CFR 201.57(f)(10)(ii)(A) and 21 CFR 201.57(f)(10)(iii)(B):

   Geriatric Use: Clinical studies of Levatol did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

   This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

4. Under the HOW SUPPLIED section, "RC22" has been changed to, "SP22" and, "Caution: Federal law prohibits dispensing without prescription" has been deleted.

5. The "Manufactured for" statement has been changed to identify Schwarz Pharma as the manufacturer and distributor.

6. "PC2077 Rev. 7/95" has been changed to "PC2077B Rev. 3/00."

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the final printed labeling included in your December 21, 2000 submission. Accordingly, the supplemental application is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call:

Ms. Zelda McDonald
Regulatory Project Manager
(301) 594-5333

Sincerely,

Raymond Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research